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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-95 (GMS)
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	REDACTED - PUBLIC VERSION
Defendants.	)	

PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR STAY

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I. NATURE AND STAGE OF THE PROCEEDING

Genentech filed this patent infringement action on January 12, 2018.[1] Celltrion has moved to dismiss or stay it. This is Genentech's answering brief in response to that motion.

II. SUMMARY OF ARGUMENT

Celltrion's contention that the Court should dismiss or stay this case in favor a "first-filed" declaratory judgment action in California no longer holds—on May 9, 2018, the California court granted Genentech's motion to dismiss that case for failure to state a claim. *See* Order Granting Defs.' Mots. to Dismiss, *Celltrion, Inc. v. Genentech, Inc.*, 4:18-cv-274-JSW (N.D. Cal. May 9, 2018) (Ex.[2] 1) ("California Order"). As no "first-filed" claims remain, Celltrion's motion should be denied. And even if Celltrion could salvage its California claims—which it cannot—the first-to-file rule still would not apply because Celltrion's California Action was anticipatory and contrary to the BPCIA.

This patent dispute arises from Celltrion's efforts to market a biosimilar of Herceptin®, a drug Genentech developed for the treatment of breast cancer. The regulatory approval scheme for biosimilars, contained in the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"). The BPCIA sets forth a "carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of infringement," including pre-litigation exchanges of information and negotiations. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). This scheme is commonly referred to as the "patent dance." *Id.*; *see also* 42 U.S.C. §§ 262(k)-(*l*).

[1] This brief refers to Defendants collectively as "Celltrion," to Plaintiffs collectively as "Genentech," and to individual parties by either their full names or the shorthand adopted by Celltrion, *see* D.I. 13 at 1.

[2] "Ex." refers to the exhibits to the Declaration of Andrew J. Danford filed with this brief.

Celltrion started but did not finish the patent dance. Rather than engage in the statutorily required negotiations designed to precede Genentech's infringement complaint under the BPCIA, 42 U.S.C. §§ 262(*l*)(4)-(6), Celltrion filed an anticipatory complaint in the Northern District of California seeking a declaration that 38 of the 40 patents Genentech identified during the parties' information exchanges are either invalid or not infringed by its proposed product. *See Celltrion, Inc. v. Genentech, Inc.*, No. 4:18-cv-274-JSW (N.D. Cal.) (the "California Action"). Genentech immediately filed this action for patent infringement in response to Celltrion's failure to continue the patent dance. Genentech chose this District because Genentech, Inc. and Teva USA, the only U.S.-based defendant, are incorporated here and because other BPCIA actions involving the same patents and Genentech product are pending here. Genentech also moved to dismiss the California Action because the BPCIA bars declaratory judgment actions by biosimilar applicants that fail to complete their obligations under the patent dance. The California court agreed, granting Genentech's motion to dismiss Celltrion's complaint in its entirety but allowing Celltrion leave to amend by June 10, 2018, if it can plead facts showing it complied with the patent dance—something it cannot do. *See* California Order (Ex. 1) at 13.

Celltrion's request that the Court defer blindly to the California Action under the first-to-file rule is now moot because there are no remaining "first-filed" claims. The rule would not apply, however, even if Celltrion were able to resurrect the California Action. The first-to-file rule does not require deference to an anticipatory action, such as a declaratory judgment action brought by a party knowing that it is about to get sued—as Celltrion did here. As the California court correctly found, the BPCIA statutorily bars such filings. *See* California Order (Ex. 1) at 8 ("Because Celltrion did not complete its obligations under Section (*l*)(5), Celltrion may not file

actions for declaratory judgment with respect to the patents at issue."); *see also* 42 U.S.C. § 262(*l*)(9)(B). Indeed, this Court recently denied a motion to dismiss in a case with nearly identical facts–an anticipatory declaratory judgment action filed in California involving Genentech's Avastin® product. *See Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-GMS, 2018 WL 503253, at *6-7 (D. Del. Jan. 22, 2018) ("*Amgen*").

The only other bases for Celltrion's motion to dismiss lack merit. Celltrion's contention that Genentech failed to plead elements of its case runs contrary to authority. Similarly, Celltrion's contention that the Court lacks personal jurisdiction over two foreign defendants ignores that both may be sued in this District based either on their future infringing conduct or under the federal long-arm statute. The scant attention that Celltrion pays to these arguments—three pages collectively—are commensurate with their seriousness; they should be rejected.

III. STATEMENT OF FACTS

Herceptin® is a genetically engineered antibody that represents a profound breakthrough in the treatment of cancer. After the FDA approved Herceptin®, the scientific community hailed it as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer" and as a sign that "the whole field of cancer research has turned a corner." D.I. 1, ¶ 4. Herceptin® has transformed the treatment of breast cancer and has become the standard of care for its patient population.

Celltrion submitted an Abbreviated Biologics License Application ("aBLA") seeking FDA approval to market a "biosimilar" of Herceptin® called CT-P6. *See* D.I. 1, ¶ 7. A biosimilar is a drug that is similar enough to the innovator product (here, Herceptin®) that the FDA will allow the biosimilar applicant to piggyback on the innovator's clinical trials during the

approval process. Celltrion and its marketing partner, Teva, hope to sell their biosimilar to the same patients who would otherwise be prescribed Genentech's Herceptin®. *See* D.I. 1, ¶ 21.

Although the filing of an aBLA is a technical act of patent infringement, the BPCIA provides for a series of exchanges and negotiation before any litigation commences. *See* 35 U.S.C. § 271(e)(2); 42 U.S.C. §§ 262(k)-(*l*); *see also Amgen*, 2018 WL 503253, at *1-2. These exchanges, known informally as the "patent dance," are designed to narrow disputes over infringement, in part by ensuring the "reference product sponsor" (Genentech) has received enough information to be able to narrow the patents to be asserted before filing suit. *See Sandoz*, 137 S. Ct. at 1670-71.

After the FDA accepted Celltrion's aBLA for filing on July 28, 2017, Genentech and Celltrion began the patent dance in an effort to continue to narrow the patents that would be at issue in the litigation everyone knew was coming. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on October 10, 2017, Genentech served a list of 40 patents that it believed could reasonably be asserted if Celltrion made, used, imported, or offered to sell CT-P6 in the United States ("Genentech's 3A List"). *See* D.I. 1, ¶ 32; Ex. 2. Celltrion continued to participate in the patent dance and served its response under § 262(*l*)(3)(B)(ii) on November 7, 2017 ("Celltrion's 3B Statement"). *See* D.I. 1, ¶ 33; Ex. 3 (cover letter for Celltrion's 3B Statement). Celltrion provided [redacted]. *See* Ex. 3 at 1. As to the remaining 38 patents, Celltrion provided non-infringement, invalidity, and/or unenforceability contentions. *See* D.I. 1, ¶ 33. Genentech provided responsive contentions on January 5, 2018, pursuant to § 262(*l*)(3)(C) ("Genentech's 3C Statement"), narrowing its focus to 18 of the original 40 patents based on

representations made in Celltrion's 3B Statement, for example, regarding Celltrion's manufacturing processes.[3] *See* D.I. 1, ¶ 34; Ex. 4 (cover letter for Genentech's 3C Statement).

Also on January 5, 2018, Genentech started the parties' required negotiations over the scope of the immediate infringement case to be filed by Genentech. *See* D.I. 1 ¶ 34. Genentech proposed that the parties litigate the 18 patents for which it provided contentions in its 3C Statement. *See id.*, ¶ 34; Ex. 4 (cover letter). Celltrion responded by letter [redacted], expressing its desire to litigate all 40 patents on Genentech's 3A List "in order to obtain certainty promptly on all patents." *See* Ex. 5. [redacted] Celltrion provided notice under 42 U.S.C. § 262(*l*)(8)(A) that it might begin commercially marketing its CT-P6 product after 180 days, i.e., [redacted]. *Id.* Then, [redacted], Celltrion filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaratory judgment of non-infringement and/or invalidity for each of the 38 patents addressed in its 3B Statement. Ex. 6.

Celltrion had obviously abandoned the patent dance. So, the next day, Genentech filed this case alleging infringement of all 40 of the patents that Celltrion contended must be litigated "in order to obtain certainty promptly." Ex. 5 at 1. Genentech filed suit here because this Court was already presiding over litigation between Genentech and two other companies about the validity and scope of many of the same patents at issue in this case.[4] Of the 40 patents at issue

[3] Genentech reserved its rights to assert these patents if Celltrion's representations proved to be false, materially incomplete, or misleading. *See, e.g.*, Ex. 3 at 8-10. Celltrion argues that "Genentech did not drop" the remaining patents on its 3A List, D.I. 13 at 5, but the BPCIA provides no more formal means to "drop" patents. The BPCIA negotiations (which Celltrion failed to complete) were the only means for determining which patents should be litigated.

[4] *See Genentech, Inc. v. Amgen, Inc.*, C.A. No. 17-1407-GMS (D. Del.) (involving claims against Amgen's biosimilar version of Genentech's Avastin biologic drug); *Genentech, Inc. v. Amgen, Inc.*, C.A. No. 17-1471-GMS (D. Del.) (same) (collectively with C.A. No. 17-1407, the

here, 26 are asserted in at least one of the other cases pending in this District and 7 are involved in all three.

Genentech also moved to dismiss Celltrion's California Action because it was anticipatory and statutorily prohibited by the BPCIA, 42 U.S.C. § 262(*l*)(9)(B). The California court agreed. On May 9, 2018 (i.e., after Celltrion filed its motion here), the California court dismissed the California Action because "Celltrion was obligated to complete all required procedures [under the patent dance] before filing this lawsuit, and it did not." California Order (Ex. 1) at 11. The court rejected Celltrion's arguments that it had complied with the statute but allowed it "leave to amend, to the extent that the identified deficiencies can be corrected consistent with counsels' obligations under Federal Rule of Civil Procedure 11," by June 10, 2018. *Id.* at 13. Celltrion has not indicated whether it intends to do so or, in light of the court's rejection of all its theories, what its Rule 11 basis for proceeding in California might be.

IV. ARGUMENT

A. This case should proceed because the California Action has been dismissed.

Celltrion's motion rests almost entirely on the first-to-file rule, arguing that the California Action should go forward before this case does. But the California Action has now been dismissed. Even assuming the first-to-file rule applies to this case—and, as explained below, there are many reasons it does not—the California case has been dismissed and this is the only one remaining. This case should therefore proceed. *See, e.g.*, *Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1348 (Fed. Cir. 2005) (holding that first-to-file rule, if it applies, only requires deference until judgment in the first case); *cf. LendingTree, LLC v. Cyber Fin. Network, Inc.*, No.

"*Amgen* cases"); *Genentech, Inc. v. Pfizer Inc.*, C.A. No. 17-1672-GMS (D. Del.) (involving claims against Pfizer's biosimilar version of Herceptin) (the "*Pfizer* case").

3:05-CV-00388, 2007 WL 2410663, at *4 (W.D.N.C. Aug. 21, 2007) (refusing to apply first-to-file rule to transfer second-filed case after first-filed case was dismissed because doing so "would allow parties to 'preemptively file a jurisdictionally defective declaratory action to claim a first-to-file right and thwart the patent holder's choice of forum' in a later action").

B. Celltrion's "first-filed" case should receive no deference.

Celltrion may attempt to argue that this Court should defer to the "first-filed" California Action until such time as it has an opportunity to amend its complaint (although it is unclear how it could do so under Rule 11consistent with the California court's order) or appeal. There is no need; the first-to-file rule does not apply here. Where "considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise," courts will look beyond the timestamps on the complaints and allow a second-filed action to proceed. *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *rev'd on other grounds*, *Wilton v. Seven Falls Co.*, 515 U.S. 277 (1995). "Exceptions" to the first-to file rule, the Federal Circuit has explained, "are not rare." *Id.*; *see also Elecs. for Imaging, Inc. v. Coyle*, 394 F.3d 1341, 1347 (Fed. Cir. 2005). Deference need not be given to anticipatory suits—that is, suits in which "the plaintiff in the first-filed action filed suit on receipt of specific, concrete indications that a suit by the defendant was imminent," *Amgen*, 2018 WL 503253, at *6 (quoting *Woodbolt Distrib., LLC v. Natural Alts. Int'l, Inc.*, C.A. No. 11-1266-GMS, 2013 WL 247041, at *4 (D. Del. Jan. 23, 2013)). Other factors weighing against application of the first-to-file rule include "the convenience and availability of witnesses, or absence of jurisdiction over all necessary or desirable parties, or the possibility of consolidation with related litigation, or considerations relating to the real party in interest." *Genentech*, 998 F.2d at 938; *see also Micron Tech., Inc. v.*

Mosaid Techs., Inc., 518 F.3d 897, 904 (Fed. Cir. 2008) (advising courts to consider "the convenience factors under 28 U.S.C. § 1404(a)" on a motion to dismiss a second-filed case).

1. *There should be no deference to the California Action because it was statutorily barred.*

Deferring to the California Action would not be "just and effective" because that case was statutorily barred. *Genentech*, 998 F.2d at 937. Biosimilar applicants' "available remedies are contingent upon their compliance with the[] steps" of the patent dance. California Order (Ex. 1) at 4. If an applicant fails to perform any of the required steps, "the applicant may not bring an action for declaratory judgment." *Id.* The California court found that Celltrion filed its lawsuit before the parties agreed a list of patents for the immediate, first-phase infringement action as set forth in 42 U.S.C. § 262(*l*)(5), a required step in the patent dance. *See id.* at 8. Thus, the court concluded that "[b]ecause Celltrion did not complete its obligations under Section (*l*)(5), Celltrion may not file actions for declaratory judgment" like the California Action. *Id.* Celltrion's non-compliance with the BPCIA is clear from these facts, the allegations in Genentech's complaint, and from the California Order, but, if Celltrion does not amend its California complaint, the Court need not wade into them—Celltrion will be collaterally estopped from disputing it here.

2. *Celltrion's California Action was anticipatory.*

The California Action is ineligible for first-filed status because it is plainly anticipatory, seeking declaratory judgments on Celltrion's perceived defenses to the infringement claims it knew Genentech was about to assert. Genentech and Celltrion were actively engaged in the patent dance. *See Sandoz*, 137 S. Ct. at 1671-72. At the time Celltrion filed the California

Action, Genentech's BPCIA complaint was, at most, 44 days away.[5] And the parties were actively working toward litigation. They negotiated a confidentiality agreement that contemplated litigation, exchanged contentions, and were in negotiations to narrow the scope of the inevitable case. Genentech proposed that the parties litigate 18 patents, D.I. 1, ¶ 34, and Celltrion proposed that they litigate 40, *id.* ¶ 35. Genentech gave every indication that it was going to file suit. Celltrion knew the suit was coming, and it knew when the suit would be filed.

Celltrion's own actions betray its understanding of just how imminent Genentech's infringement complaint would be if it broke off the patent dance. Celltrion filed the California Action [redacted] after it wrote to Genentech to end the parties' negotiations. *Compare* Ex. 5 (correspondence from Celltrion received [redacted]), *with* Ex. 6 (notice of electronic filing for California Action [redacted]). And despite knowing that Genentech was represented by multiple lawyers in the Bay Area, Celltrion sent its letter ***only*** to Genentech's lawyers on the East Coast, [redacted]. *See* Ex. 5. Simply put, a party does not try to hide the event that (allegedly) opens the courthouse doors and file a declaratory judgment action [redacted] unless it knows that it is about to get sued elsewhere.

Celltrion's California Action is anticipatory for the same reasons that this Court and Judge Wu in the Central District of California found Amgen's essentially identical California action to be anticipatory earlier this year. *See Amgen*, 2018 WL 503253, at *7; *Amgen*, 2018 WL 910198, at *4 ("[G]iven the parties' significant exchanges under the BPCIA and the timing of Amgen's lawsuit, although Amgen's lawsuit was first filed, it was highly anticipatory.").

[5] When Celltrion filed its complaint, nine days remained in the § 262(*l*)(4) negotiation period. Had no agreement been reached, the parties would have exchanged lists under § 262(*l*)(5)(B) within 5 days and Genentech would have sued Celltrion per § 262(*l*)(6)(B) within 30 days.

Celltrion's only attempt to distinguish that case—arguing that Amgen had greater certainty that Genentech would sue it because Genentech had already sued it to enforce compliance with the patent dance, D.I. 13 at 12—has no merit because that earlier suit was not one for patent infringement. *See Amgen*, 2018 WL 503253, at *1 (describing the first *Amgen* case, C.A. No. 17-165-GMS). Here, as in the *Amgen* dispute, "Plaintiffs [i.e., Genentech] continued to participate in the patent dance, and were waiting for a response from [Celltrion], when [Celltrion] filed its California action." *Id.* at *7. Here, as there, "the California action was anticipatory." *Id.* (holding that an anticipatory action is not entitled to deference if convenience factors do not favor litigating in first-filed district).

3. *The* Jumara *convenience factors favor litigating this dispute in this District.*

Either the anticipatory nature of Celltrion's California Action or the fact that it has been dismissed for failure to state a claim is enough to deny Celltrion's motion to dismiss. But, to the extent the Court considers convenience factors as well, *see, e.g.*, *Mitek Sys., Inc. v. United Servs. Auto. Ass'n*, C.A. No. 12-462-GMS, 2012 WL 3777423, at *3 (D. Del. Aug. 30, 2012), the "private interest" and "public interest" factors favor litigating this dispute in this District, *see, e.g.*, *Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879-80 (3d Cir. 1995). Although Celltrion has the burden of persuading the Court that this action is better heard elsewhere, *see, e.g.*, *Smart Audio Techs., LLC v. Apple, Inc.*, 910 F. Supp. 2d 718, 724 (D. Del. 2012), it fails to cite the controlling case law in this Circuit (*Jumara*) or to address many of the relevant factors. D.I. 13, at 15-18. The *Amgen* case, however, leaves Celltrion little room for argument—here, as there, "the *Jumara* factors . . . weigh against giving the California action priority status." *Amgen*, 2018 WL 503253, at *7.

(i) *The private interest factors favor litigation in this District.*

Chief among the private interest factors is a plaintiff's choice of forum, which "is entitled to 'paramount consideration,' and should not lightly be disturbed." *Mallinckrodt, Inc. v. E–Z–Em Inc.*, 670 F. Supp. 2d 349, 356-57 (D. Del. 2009) (quoting *Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir. 1970)). Genentech chose to sue in Delaware, where Genentech has long been incorporated, D.I. 1, ¶ 10, where Genentech has other cases involving the same patents and products pending, *see infra* § IV.B.3(ii), and where Teva USA, the only U.S.-based defendant, is incorporated, *id.* ¶ 19. There is no reason to discount Genentech's decision to sue on its own "home turf" or to sue the only domestic defendant where it is at home.[6] *See Amgen*, 2018 WL 503253, at *3.

The remaining private interest factors are neutral or favor this District. None of the defendants have a principal place of business or headquarters in California, so the Court owes no deference to any preference that they may have to litigate there. *Cf. id.* (finding that Amgen's preference to litigate in California did not outweigh Genentech's preference to litigate in Delaware despite Amgen's headquarters in California). Celltrion's product was developed abroad and, if approved, will be sold nationwide. This is a reasonable and appropriate district in which to litigate its infringement. *Id.* at *4. The defendants are large biotechnology organizations with a global footprint, so they cannot credibly claim that litigating in this District (relative to California) would pose an undue financial burden. *Id.* (citing *Bristol-Myers Squibb*

[6] Celltrion repeatedly argues that Genentech cannot object to litigating in California, where it maintains its principal place of business. D.I. 13 at 1-2, 5, 7, 13, 15-16. This echoes the argument raised by Amgen that Delaware is not Genentech's "home turf." But, as this Court recognized in *Amgen*, "there is a line of cases from this District that construe a plaintiff's 'home turf' to include its state of incorporation, which for Genentech is Delaware," and "even in cases where Delaware is not considered a plaintiff's 'home turf,' a plaintiff's choice of forum is still accorded 'substantial weight.'" *Amgen*, 2018 WL 503253, at *3. No weight should be given to Celltrion's repackaged "home turf" argument.

Co. v. Merck & Co., C.A. No. 14-1131-GMS, 2014 WL 13683600 (D. Del. Apr. 29, 2015)). Indeed, Teva USA's decision to incorporate in Delaware belies any hardship claims it may raise, as do Celltrion's decisions to repeatedly initiate BPCIA-related litigation on the East Coast. *See Celltrion Healthcare Co., Ltd. v. Janssen Biotech, Inc.*, No. 1:14-cv-11613-MLW (D. Mass.); *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, No. 1:14-cv-2256-PAC (S.D.N.Y.). And although many of Genentech's witnesses and records are in California, defendant Teva USA—which "will market and distribute Celltrion's aBLA product in the United States upon FDA approval," D.I. 1, ¶ 21, and therefore will have many relevant witnesses and documents—is headquartered less than 50 miles from Wilmington. *See* D.I. 1, ¶ 19.

(ii) *The public interest factors favor litigation in this District.*

Two public interest factors are relevant for this dispute—"practical considerations that could make the trial easy, expeditious, or inexpensive" and "the relative administrative difficulty in the two fora resulting from court congestion." *Jumara*, 55 F.3d at 879-80. Both favor resolving this dispute in this District.[7]

There is little doubt that litigating this dispute in Delaware will be easier and less taxing on the judicial system. This Court is presiding over three other BPCIA actions, the *Pfizer* case and the *Amgen* cases, involving Genentech's products (including Herceptin) and patents. *See supra* note 4. The *Pfizer* case involves another proposed biosimilar of Herceptin®, the reference product at issue in this case, as well as 19 of the same patents that Genentech has asserted against Celltrion here. Discovery has just begun in the *Pfizer* case, and no trial date is set. The *Amgen*

[7] The remaining *Jumara* public interest factors are neutral. The enforceability of the judgment, the public policies of the fora, and the familiarity of the trial judge with the applicable state law are inapplicable because Genentech has asserted only federal claims. The local interest in deciding local controversies at home is neutral because Genentech is at home in both districts.

cases also involve a proposed biosimilar of Avastin®, a different Genentech product, and 14 of the patents at issue in this case. So, regardless of whether this case is heard in Delaware or California, this Court will consider many of the same patents, claims, and issues and will hear from many of the same witnesses. It is simply more efficient for this Court to leverage that experience—coordinating the cases where practicable—than to send this case to another court that will not otherwise need to engage with these issues.

Celltrion's three responses are unpersuasive.

First, Celltrion argues that hearing this case in California is preferable because Celltrion has brought another declaratory judgment action involving a different Genentech drug there (Rituxan®, which is not the subject of any litigation before this Court). D.I. 13 at 16. But that case has also been dismissed for failure to state a claim, *see* California Order (Ex. 1) (dismissing both cases); Celltrion should not be permitted to bootstrap one improperly filed action with another. By contrast, both the *Pfizer* and *Amgen* cases will proceed in this District. And even if Celltrion's other case were to be revived in California, there are simply fewer efficiencies gained by coordinating this case with one about a different drug than with one about Herceptin®—i.e., the *Pfizer* case in this Court. So even if litigating in California were more efficient for Celltrion (which, as noted above, is hardly clear), it certainly is not more efficient for Genentech or the courts, which would need to address many of the same issues in parallel on opposite coasts.[8]

[8] Celltrion argues that Genentech is causing such inefficiencies by seeking to litigate the case about Celltrion's biosimilar of Rituxan® in New Jersey. *See* D.I. 13 at 16-17. Not so. When Celltrion filed its California suit for that product, there was already another action involving that drug and another party in New Jersey. *See Genentech, Inc. v. Sandoz, Inc.*, No. 1:17-cv-13507-RMB-KMW (D.N.J.). Genentech's complaints keep all the Herceptin® and Avastin® cases in Delaware and all the Rituxan® cases in New Jersey; Celltrion's position would divide the cases for each product across the country.

Second, throughout its brief, Celltrion hints that that the California Action should proceed because it is more advanced than this one. *See, e.g.*, D.I. 13 at 9 n.3. That is not correct, as the only way the California Action can continue is if Celltrion files a new complaint and starts over (and, again, it is not clear how Celltrion could file such a complaint consistent with its Rule 11 obligations). And the California Action has not moved past the pleading stage; the California court is no more steeped in the subject matter of this case than this Court. *See Amgen*, 2018 WL 503253, at *5.

Finally, Celltrion argues that the inability to ***completely*** coordinate this case with the *Pfizer* and *Amgen* cases weighs against keeping the case in this District, but that is nonsensical. *See* D.I. 13 at 17. To be sure, this case is different from the *Pfizer* and *Amgen* cases—it involves a different party (Celltrion), a different accused product (CT-P6), and, for the *Amgen* cases, a different Genentech product (Herceptin®). But it shares many of the same patents, technology, claims terms, documents (and associated discovery issues), and witnesses. That overlap creates the opportunity for efficiencies—efficiencies that Genentech has already sought to realize. *See* D.I. 15 at 8 (joint status report in the *Pfizer* case addressing possible coordination with this case). And there is no reason to disregard the "familiarity or expertise over [the] patented technology" that this Court will develop simply because complete coordination is not possible. *Amgen*, 2018 WL 503253, at *5.

As to the second *Jumara* public interest factor, court congestion, there is little doubt that this action would provide "the legal certainty necessary to bring their products to market," D.I. 13 at 1, faster than the California Action. The time-to-trial in patent cases is an "illuminating measure of court congestion." *Amgen*, 2018 WL 503253, at *6. According to the same study that the Court considered in *Amgen*, the Northern District of California has one of the longest

times-to-trial of all patent-heavy districts—over six months longer than this District's. *See* Ex. 7 at 22 (median time-to-trial in patent cases is 2.1 years in this District versus 2.6 years in the Northern District of California). This Court, not the California court, is better positioned to give the parties they relief they seek.

C. Genentech has adequately pleaded claims for patent infringement and declaratory judgments based on Celltrion's aBLA filing and notice of commercial marketing.

In the final three pages of its brief, Celltrion recites a laundry list of alleged deficiencies in Genentech's complaint for which it seeks to dismiss either for failure to state a claim or for lack of personal jurisdiction. Celltrion provides almost no detail or authority to support these arguments—because none exists. These conclusory and baseless challenges should be rejected.

Celltrion's chief complaint appears to be that Genentech did not plead facts sufficient to demonstrate that Celltrion infringes each of the asserted patents. It ignores, however, that the statutory provision giving rise to Genentech's claims, 35 U.S.C. § 271(e)(2), has different elements from a traditional patent infringement claim about a product that is already on the market. *See* D.I. 1, ¶ 9. As relevant to this case, § 271(e)(2) provides:

> (e)(2) It shall be an act of infringement to submit—
>
> (C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act (including as provided under section 351(*l*)(7) of such Act) [i.e., a 3A List], an application seeking approval of a biological product…
>
> if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

Genentech pleaded that Celltrion submitted an aBLA seeking approval to market CT-P6, that each of the 40 patents-in-suit was identified in Genentech's 3A List for CT-P6, and that Celltrion

is seeking to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of CT-P6 before the patents expire. *See, e.g.*, D.I. 1, ¶¶ 7, 9, 30, 94. At least with respect to 38 of the 40 patents-in-suit, Celltrion does not dispute this. These allegations are all that are necessary to state a claim under 35 U.S.C. § 271(e)(2) for each patent.

Yet, even if more were required to state a claim for infringement of these patents, Genentech has provided it. A plaintiff need only "state a claim to relief that is plausible on its face," *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007), which is done when "the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Specific facts," the Supreme Court has held, "are not necessary; the statement need only 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (internal quotation marks omitted) (alteration in original) (quoting *Twombly*, 550 U.S. at 555). In the context of a claim for patent infringement, the Federal Circuit has found the *Twombly*/*Iqbal* standard satisfied if a plaintiff identifies the accused products, attaches the patents, and alleges that the accused products meet each and every element of at least one of the claims. *See, e.g.*, *Disc Disease Solutions Inc. v. VGH Solutions, Inc.*, --- F.3d ---, No. 2017-1483, 2018 WL 2011468, at *3 (Fed. Cir. May 1, 2018). Genentech's complaint does all of that. *See, e.g.*, D.I. 1, ¶¶ 95-96 (identifying CT-P6 as the accused product, noting that it will infringe the asserted patent under specified subsections of 35 U.S.C. § 271, and explaining that this infringement gives rise to liability under 35 U.S.C. § 271(e)(2)(C)(i)); *id.* Exs. A-NN (attaching patents). Moreover, for many of the asserted patents, Genentech's complaint does much more than this, directing Celltrion to detailed claim charts explaining the

basis for its infringement allegations for the patents that Genentech proposed litigating in the first-phase infringement action. *See, e.g.*, D.I. 1, ¶ 95.

Celltrion also argues that Genentech's claims for infringement and a declaratory judgment of infringement [redacted]. *See* Ex. 3 at 1; D.I. 13 at 4. Even taking this unsworn representation as true, Celltrion overstates the content of its representation. Celltrion has never represented, to Genentech or this Court, that it is not seeking FDA approval of its application for CT-P6 [redacted] or that it will not "engage in the commercial manufacture, use, or sale" of CT-P6 [redacted]. Accordingly, Genentech has adequately stated a claim for infringement of these patents under 35 U.S.C. § 271(e)(2)(C)(i), and an active controversy exists regarding whether Celltrion will engage in actions that will infringe these two patents. Celltrion's motion should therefore be denied or, should the Court determine otherwise, Genentech should be granted leave to amend.

D. This Court has personal jurisdiction over the foreign defendants under the federal long-arm statute and based on their future sales in this District.

Celltrion's challenge to personal jurisdiction is equally meritless. It contends that two foreign defendants, Celltrion Healthcare and TPIG, are not subject to either general or specific personal jurisdiction in this District or any other because they "are neither incorporated nor headquartered anywhere in the United States" and did not submit the aBLA at issue in this case. (D.I. 13 at 20.) But those facts fail to show that personal jurisdiction is improper in this District. Either specific jurisdiction exists under *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755, 759-63 (Fed. Cir. 2016), because Celltrion Healthcare and TPIG "will market their proposed biosimilar product in Delaware if approved" (D.I. 1, ¶ 27) or "this Court has personal

jurisdiction over [Celltrion Healthcare and TPIG] pursuant to Federal Rule of Civil Procedure 4(k)(2)" (D.I. 1, ¶¶ 27, 29), the federal long-arm statute, because neither is subject to general or specific jurisdiction in any district.

Celltrion notably does not challenge personal jurisdiction over Celltrion Inc., the foreign entity that filed the aBLA. That is because the Federal Circuit has clearly held that such "filings, including its certifications regarding the patents at issue here"—like Celltrion's 3B Statement—"have a substantial connection with Delaware because they reliably, non-speculatively predict Delaware activities by [the filer]." *Acorda*, 817 F.3d at 762. Courts have extended *Acorda*'s holding to find specific jurisdiction over an applicant's affiliates that will market and sell the drug that is the subject of the application in the district. *See, e.g.*, *Helsinn Healthcare S.A. v. Hospira, Inc.*, No. CV 15-2077 (MLC), 2016 WL 1338601, at *6 (D.N.J. Apr. 5, 2016) (finding specific jurisdiction over non-applicant marketer and distributor post-*Acorda*). Because Celltrion, Inc., Celltrion Healthcare, and TPIG entered into an exclusive partnership to commercialize CT-P6 in the United States, D.I. 1, ¶ 21, specific jurisdiction in this District is appropriate under *Acorda*. Celltrion's cited cases, all from outside the drug-approval and 35 U.S.C. § 271(e)(2) contexts, are inapposite because they fail to account for the future infringing activities that, according to *Acorda*, give rise to specific jurisdiction. *See DNA Genotek Inc. v. Spectrum DNA*, 159 F. Supp. 3d 477 (D. Del. 2016) (accusing saliva test kit of infringement); *Shuker v. Smith & Nephew PLC*, 885 F.3d 760 (3d Cir. 2018) (products liability case).

In any case, even accepting Celltrion's allegations that specific jurisdiction is not appropriate over these two entities, its motion still fails because the federal long-arm statute, Fed. R. Civ. P. 4(k)(2), "allow[s] a court to exercise personal jurisdiction over a defendant if (1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any

state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process." *See Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com. de Equip. Medico*, 563 F.3d 1285, 1293-94 (Fed. Cir. 2009). As to the first prong, claims for patent infringement, like Genentech's claims in this case, arise under federal law. *See id.* at 1294. As to the second prong, the Federal Circuit allows a defendant to avoid application of the federal long-arm statute "only when it designates a suitable forum in which ***the plaintiff*** could have brought suit." *Touchcom, Inc. v. Bereskin & Parr*, 574 F.3d 1403, 1415 (Fed. Cir. 2009) (emphasis added). Celltrion has offered no such alternative forum here; even though Celltrion sued Genentech in California, Celltrion has offered nothing to show that Genentech could have sued it there. Accordingly, this Court need only consider the due process analysis, which requires that a nonresident "have certain minimum contacts . . . such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014) (quotation marks omitted) (quoting *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). This analysis, in the context of the federal long-arm statute, weighs whether "(1) the defendant purposefully directed its activities at residents of the [United States], (2) the claim arises out of or relates to the defendant's activities with the [United States], and (3) assertion of personal jurisdiction is reasonable and fair." *See Synthes*, 563 F.3d at 1297-98. When a party has purposefully directed its activities at the United States, it "must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable" to avoid it. *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 477 (1985); *see also Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1568 (Fed. Cir. 1994) (characterizing cases in which an adverse "reasonable and fair" finding outweighs the others a "rare situation").

Celltrion Healthcare and TPIG meet each of these factors. Celltrion Healthcare and TPIG entered into an exclusive partnership to commercialize Celltrion's product in the United States. D.I. 1, ¶ 21. By agreeing to seek approval to market their drug in the United States and by agreeing to sell it to healthcare providers and patients in the United States once approved, Celltrion Healthcare and TPIG purposely directed their activities at U.S. residents. Genentech's claims—all for patent infringement arising out of that application and future U.S. sales—arise out of Celltrion Healthcare and TPIG's U.S. activities. Celltrion has made no effort to show that jurisdiction here would not be "reasonable and fair," nor could it. Both entities have litigated on the East Coast before, and TPIG has done so in this District, *see, e.g.*, *Celltrion Healthcare Co., Ltd. v. Kennedy Trust for Rheumatology Research*, No. 1:14-cv-2256-PAC (S.D.N.Y. filed Mar. 31, 2014); *Teva Pharms. Int'l GmbH v. Slayback Pharma LLC*, C.A. No. 1:18-cv-00117-GMS (D. Del. filed Jan. 19, 2018). Litigating this case in Delaware would also advance judicial efficiency because other cases involving Herceptin® biosimilars and many of the same patents are currently before this Court. *See generally Pfizer Inc. v. Mylan Inc.*, 201 F. Supp. 3d 483, 489 (D. Del. 2016) (finding exercise of specific jurisdiction appropriate on similar facts).

There is no doubt that it would be reasonable and fair for this Court to exercise jurisdiction over Celltrion Healthcare and TPIG. But, should the Court need additional evidence to this effect, Genentech respectfully requests that it be granted leave to take jurisdictional discovery and thereafter file a supplemental opposition to Celltrion's motion to dismiss. *See Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003).

V. CONCLUSION

Genentech respectfully requests that the Court deny Celltrion's motion to dismiss or stay.

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CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 21, 2018, upon the following at the email addresses indicated below:

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